CLEAN AIR TASK FORCE

Comments of James Duffy, Clean Air Task Force, Associate Attorney
at Strengthening Transparency in Regulatory Science Public Hearing
July 17, 2018, Washington DC

Good afternoon, my name is James Duffy and I am an associate attorney with Clean Air Task Force. CATF seeks to help safeguard against the worst impacts of climate change by working to catalyze the rapid global development and deployment of low carbon energy and other climate-protecting technologies, through research and analysis and public advocacy leadership.

EPA's Proposal, at best, is a solution in search of a problem – the Agency has failed to identify a need for further review of the already, extensively peer-reviewed public health and environmental science it uses in decision-making. Nor has it made the case that underlying health data must be made more public that current statutes and practice allow. The only thing transparent about the Proposal, is that it is an attempt to undermine EPA's use of the "best available science" by placing arbitrary limits on the ability to consider the best studies.[1] As the professor cited multiple times in the Proposal recently said, if the Proposal is finalized, "science will be practically eliminated from all decision-making processes," so that public health and environmental "regulation would then depend … on opinion and whim."[2]

Banning the use of fully peer-reviewed studies because their underlying data must be kept confidential would eliminate the consideration of vital information in critical public health decision-making. That is not only unnecessary, it also represents a significant shift in decades-long policy, without justification.[3] As the D.C. Circuit has held when considering this very question: "requiring agencies to obtain and publicize the data underlying the studies on which they rely would be impractical and unnecessary."[4] Congress has clearly spoken, moreover, mandating that Agencies must consider *all* relevant science.[5]

It is well understood, and has been for decades, that many of the most important public health studies are those based on actual patient information. Because that information must be kept highly confidential, and because making even some of the patient's details public would allow them to be identified, the information must be kept private.[6]

But that does not mean those studies can't be - or haven't been - verified. For example, the Harvard Six-Cities Studies, linking fine particulate matter and mortality, have been extensively re-analyzed by independent institutions, including by researchers under the auspices of the Health Effects Institute. This reanalysis confirmed the studies essential findings while keeping confidential the underlying data.[7]

There are already several ways in which the public can access the studies that EPA uses, and in some cases their underlying data, without the release of confidential information - including the Freedom of Information Act, which provides an avenue to request raw data, including a process ensuring that sensitive data is protected.

The Proposal puts EPA in the untenable position of either violating its mandate to consider all relevant science or violating confidentiality laws.

Additionally, the Proposal is impermissibly scattershot, vague and confusing. It is insufficiently formed to allow for meaningful comment – it seems more like a request for ideas about how to discredit the best available science, than for how to make it more accessible.[8] For example, the Proposal claims that it is consistent with the Data Quality Act and HIPAA, as well as various Executive Orders, but each of these contains checks on the release of confidential information. In fact, the longstanding OMB Guidelines, stemming from the Data Quality Act, recognize peer review as a *per se* marker of objectivity, and the Harvard Six Cities Studies reanalysis as the gold standard for reproducibility.[9]

Finally, in violation of Executive Order 12,866, the Proposal fails to perform any analysis regarding the impact this rulemaking could have on the environment, public health or science generally - or even on what it would cost to implement. Because the Agency does not have authority to undertake this effort, and because it would undermine consideration of relevant science in its public health and environmental rulemakings, it should be abandoned.

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[1] Bob Sussman, "EPA's Flawed 'Secret Science' Plan Puts Good Science at Risk," BLOOMBERG BNA (May 21, 2018), *available at*: https://www.bna.com/practitioner-insights-epas-n57982092715/.

[2] John P. A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS MED. 5 (May 3, 2018).

[3] EPA has long held that "whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications." EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (Nov. 29, 2016) (emphasis added).

[4] *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2001); *Coal. of Battery Recyclers Ass'n* v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010) (same).

[5] 5 U.S.C. § 553(c) (requiring "consideration of the relevant matter presented"). *Hercules, Inc. v. EPA*, 938 F.2d 276, 289 (D.C. Cir. 1991)(rejecting "the EPA's action because it reads into the statute a drastic limitation that nowhere appears in the words Congress chose and that, in fact, directly contradicts the unrestricted character of those words.").

[6] National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties*, at 11 (2002), *available at*: https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing.

[7] *Id.* at 11-12

[8] *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977).

[9] 67 Fed. Reg. 8,452, 8,456 (Feb. 22, 2002).